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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,091	11/25/2003	Jose Remacle	4044.001	7897

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,091	REMACLE, JOSE	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-20 are pending and under examination.

Withdrawn Rejection and Objection

In view of the amendments to the claims the objection to the specification is withdrawn. Also, the following rejections are withdrawn: 35 USC 112, second paragraph; 35 USC 102 (b) over MacBeath and 35 USC 103 over MacBeath in view of Lauks and Lazar.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Decker et al(GB 2,016,687). [Based on the species beads as being the broad claimed microarray, as claimed.]

Decker discloses at pages 2 up to 5 an immunoassay method for the detection and determination of antigens and antibodies. The method comprises an indirect application of an antibody or antigen to a solid support (a selected capture protein, as claimed). It generally involves the procedure in which the solid support is precoated with antigen or antibody to potentiate the adherence of the antibody or antigen. The reagents consist of a solid support that has been coated either directly or indirectly with an antigen or antibody and stabilized with a sugar coating to impart a storage capability. The percent of sugar e.g., xylitol, mannitol and sorbitol is given in Table II. Accordingly, the specific method steps of Decker employing specific components fully meet the broad claimed method.

Claims 1-5, 8-10 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Devereaus et al (WO 93/07466).

Devereaus fully meets the claimed method as disclosed at e.g., page 14, line 16(i.e., the use of .1-50% of polyol,

specifically arabitol and xylitol) up to page 15, line 25. See specifically the EXAMPLES, which provide a detail description of the claimed method using specific components in the array.

Claims 1-3, 5 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Stillman et al (20030175827). Stillman discloses at paragraph [0010] a method for producing a thin film dried protein composition comprising making a protein containing solution that is to be dried on a surface, preferably a biologically active protein. (For the purposes of the present invention, the term "biologically active" includes any protein that can participate in a specific binding reaction, (such as antibodies, antibody fragments, antigens, antigen fragments), as well as peptides or enzymes.) The solution is made with a buffer that maintains the surface pH between about 5.0 and 9.0 during solution drying and with a saccharide in an amount sufficient to stabilize the protein during solution drying. The selection of the pH should consider the optimal pH for the biologically active protein. The solution is then applied to a support having the surface for depositing, the surface having a protein denaturing capability. Thin film of protein containing solution is allowed to dry on the support surface under normal pressures. At paragraph [0011] the method enables one to make stable thin film dried protein compositions. Such films can be incorporated

into protein analytical devices. Of particular interest are proteomic microarrays.

Claim Rejections - 35 USC § 103

Claims 1-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Decker or Devereaus or Stillman in view of either Guo(Faming Zhuanli Shenqing Gongkai) or Sandford (US 2003/0134294).

Each of Decker, Stillman and Devereaus is discussed above. Each of these references does not disclose the use of antiseptic as sodium azide. However, Guo discloses in the abstract a method in which a protein chip with array of 10-10,000 cm-1 and array size of 5-500 consists of the activated carrier and spotting solution. The spotting solution is composed of probe (such as antigen, antibody, drug receptor, agglutinin, cell, or tissue), fucose, antiseptic (such as Na azide) and C2-10 aliphatic polyol. The protein chip is manufactured by spotting the mixture of probe and spotting solution on the activated carrier sheet, and then blocking with bovine serum. The protein chip may be used to detect, recognize, and identify the antigen, antibody, medicine or its receptors, polysaccharide, agglutinin, tissue, or cell. Sandford discloses at paragraph [0197] that

preservatives like azide are effective to retard or prevent microbial proliferation. Sandford discloses at paragraph [0199] Lyoprotectants are effective to reduce or prevent chemical or physical instability of a protein upon lyophilization and storage. Examples of a polyol such as trihydric or higher sugar alcohol (e.g., glycerin, erythritol, glycerol, arabitol, xylitol, sorbitol, and manmitol). Sandford also discloses the use of borate buffer. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use azide in the method of either Decker or Stillman or Devereaus as taught by either Sandford or Guo. The advantages taught by Sandford or Guo would provide the motivation to one having ordinary skill in the art as to the known use of azide as a preservative.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Decker or Devereaux or Stillman in view of either Guo(Faming Zhuanli Shenqing Gongkai) or Sandford (US 2003/0134294) as applied to claims 1-15 and 18-20 above, and further in view of in view of Moreadith (USP 6632934).

Each of Decker, Stillman and Devereaus does not disclose that the microarray containing protein can be stored for more than six months. Moreadith discloses at col. 24, lines 23-35

In general, due to the relative stability of peptides, they may be readily stored in aqueous solutions for fairly long periods of time if desired, e.g., up to six months or more, in virtually any aqueous solution without appreciable degradation or loss of antigenic activity. However, where extended aqueous storage is contemplated it will generally be desirable to include agents including buffers such as Tris or phosphate buffers to maintain a pH of about 7.0 to about 7.5. Moreover, it may be desirable to include agents which will inhibit microbial growth, such as sodium azide. For extended storage in an aqueous state it will be desirable to store the solutions at about 4.degree. C., or more preferably, frozen. Of course, where the peptides are stored in a lyophilized or powdered state, they may be stored virtually indefinitely, e.g., in metered aliquots that may be rehydrated with a predetermined amount of water (preferably distilled) or buffer prior to use. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to store the composition of any one of Decker or Stillman and Devereaus for more than six months as taught by Moreadith. Each of Decker, Stilmann or Devereaus teaches polyol as a stabilizer as similarly claimed. [Note that Decker teaches said storage for a long period of time employing

the polyol as stabilizer except did not positively teach the length of time i.e., months it can be stored.]

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Decker et al (GB 2,016,687A) in view of Brennan et al US 2005/0053954) or applicants' disclosure of prior art. [This rejection is based on microarray, as broadly claimed.]

Decker discloses at page 2, 15 up to page 6, a method of making beads by applying an antibody or antigen to a solid support comprising coating the solid support as beads with antigen or antibody to potentiate the adherence of the corresponding antibody or antigen; maintaining the avidity and antigenicity of the exposed immunoadsorbent by applying a sugar coat e.g., 10% mannitol, sorbitol, inter alia, in PBS (Table 1, page 3) and soaking for 30 minutes at room temperature. The bead was then allowed to dry at room temperature. See specifically the Examples, pages 3-5. Decker uses beads but not the broad claimed microarray. Brennan et al discloses that microarray can be a single component protein or multiple protein components. Brennan further discloses at page 1, [0002]-[0004] that a microarray has the advantage of being scalable, and their ordered nature lends itself to high - throughput screening using robotics techniques. Microarrays have

revolutionized methods for high throughput analysis for several DNA experiments; including gene expression. Applicants discloses at page 8, [00041] that in general, the concentration of the polyol contained in the spotting solution may preferably be in the range of between about 0.5 to 10 %, preferably 1 % and 5 %, to show the desired effect. [00042] The aqueous solution containing the polyols may also contain an anti-bacterial agent, such as azide, which may be present in the solution in a concentration of between 0.01 and 0.5%, and preferably between 0.05 and 0.2 %, or borate at a concentration between 1 and 100 mM, and preferably between 25 and 75 mM. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use microarray besides the beads of Decker as taught by Brennan for the advantage derived in the use of microarray e.g., high throughout screening. The numerous advantages provided by Brennan supra would provide the motivation to one having ordinary skill in the art at the time of filing. Furthermore, as disclosed by applicants the amount of components such as polyol, azide and borate that can be used in a composition are generally the amount known in the art. See e.g., Decker. It would be within the ordinary skill in the art to determine said result effective concentration.

Applicants' arguments in the last Office action are moot in view of the above rejections.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
April 3, 2006